

REMARKS

Claims 56-71 are pending in the present application.

At the outset, Applicants wish to thank Examiner Swartz for the indication that the previous rejections have been overcome (see paper number 25, paragraphs 4 and 5). In addition, Applicants wish to thank Examiner Swartz for the indication that Claim 71 is allowable (see paper number 25, paragraph 11).

The rejections of Claims 58 and 59 and of Claims 60-70 under 35 U.S.C. § 112, second paragraph, have been obviated by appropriate amendment.

With respect to the Examiner's confusion of the term "units," Applicants have amended Claims 58 and 59 to replace this term with "epitope units." Applicants submit that the skilled artisan would readily understand the meaning of this term. However, to further emphasize the definiteness of this term, Applicants wish to draw the Examiner's attention to page 31, lines 15-28 and page 36, lines 19-27 of the specification where this term is described. For example, on page 31, lines 24-26, Applicants state:

By an epitope or an epitope unit according to the present invention is meant a portion of the LHP polypeptide which is delineated by the area of interaction with antibodies that are specific to LHP, in particular monoclonal antibodies directed against LHP.

As the Examiner will also note, Applicants have amended Claim 60. As such, Claim 60 and, to the extent that they depend from Claim 60, Claims 61-70 are free of the criticisms set forth in paragraph 9 of paper number 25.

Thus, these rejections are no longer tenable and should be withdrawn.

The rejection of Claims 56-70 under 35 U.S.C. § 112, second paragraph, is obviated in part by amendment and traversed in part.

At the outset, Applicants note that embodiment (f) and (g) of Claim 56 have been deleted, which is requested without prejudice toward further examination in an ensuing continuation application. Therefore, cancellation of embodiment (f) and (g) of Claim 56 is believed to obviate a substantial portion of this ground of rejection.

The Examiner has also issued this ground of rejection based on usage of the phrase “a biologically active polynucleotide derivative.” In so doing, the Examiner has individually focused on the terms “biological activity” and “derivative.”

First, Applicants wish to remind the Examiner that: “Applicants are their own lexicographer” (MPEP §2173.01). MPEP §2173.01 also states that Applicants “can define in the claims what they regard as their invention essentially in whatever terms they choose so long as the terms are not used in ways that are contrary to accepted meanings in the art.” Further, definiteness of claim language must be analyzed, not in a vacuum, but in light of:

- (A) The content of the particular application disclosure;
- (B) The teachings of the prior art; and
- (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made (MPEP §2173.02).

Applicants submit that a clear definition of the phrase “a biologically active polynucleotide derivative of SEQ ID NO 2” can be ascertained by analyzing this phrase in view of the specification and the level of ordinary skill in the art at the time the invention was made. Specifically, Applicants wish to draw the Examiner’s attention to the specification at page 16, line 26 to page 17, line 11, which explicitly defines the objected to phrase, stating:

By a biologically active polynucleotide derivative of SEQ ID NO 2 or SEQ ID NO 3 according to the present invention is meant a polynucleotide comprising or alternatively consisting in a fragment of said polynucleotide which is functional as a regulatory region for expressing a recombinant polypeptide in a recombinant cell host.

More specifically, a typical biologically active polynucleotide derivative of SEQ ID NO 2 or SEQ ID NO 3 is a polynucleotide comprising at least the nucleotide region containing one transcription start site chosen from among the transcription start sites respectively located at the nucleotide in position 454 of SEQ ID NO 1 and at the nucleotide position 513 of SEQ ID NO 1.

In a particular embodiment of a biologically active polynucleotide derivative of SEQ ID NO 2 or SEQ ID NO 3 the ribosome binding site (shine Dalgarno sequence) which is located from the nucleotide at position 508 to the nucleotide at position 512 of SEQ ID NO 1 may be removed or absent and optionally replaced by a suitable natural or synthetic ribosome binding site, depending on the recombinant cell host in which its expression is desired.

To obtain a further understanding of the objected to phrase and its definition above, the Examiner is referred to page 12, lines 10-27, page 13, line 24 to page 16, line 25, and the Sequence Listing, which define the scope of the invention and the claimed sequences. For example, at page 12, lines 10-14, Applicants state:

The present inventors have discovered a new polynucleotide and have shown that said polynucleotide contained a whole operon consisting in a regulatory region containing a functional promoter and a functional ribosome binding site that drives the expression of two structural genes respectively encoding a new polypeptide named LHP and an already known polypeptide named ESAT-6.

Further, at page 12, lines 24-27, Applicants state:

Moreover, the present inventors have shown that the regulatory region located at the 5' end of the open reading frame coding for LHP can be successfully used to drive the expression of an heterologous polynucleotide as regards to LHP in a recombinant cell host.

Based on the foregoing, Applicants submit that the objected to expression is fully

defined in the specification so as to be understood by "one possessing the ordinary level of skill in the pertinent art." Moreover, since nothing in the expression "a biologically active polynucleotide derivative" could reasonably be deemed to be "contrary to accepted meanings in the art," Applicants submit that this phrase is definite within the context of 35 U.S.C. §112, second paragraph.

Applicants request withdrawal of this ground of rejection.

Applicants submit that the present application is now in condition for allowance.

Early notification of such action is earnestly solicited.

Respectfully submitted,

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